

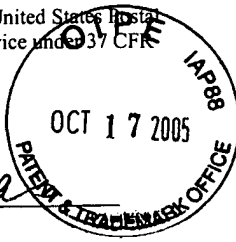
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PATENT  
Attorney Docket No.: 010692-004532US

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By: Marta Vanegas



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Gorfine, Stephen R.

Application No.: 10/669,099

Filed: September 22, 2003

For: NITRIC OXIDE DONOR  
COMPOSITION AND METHOD FOR  
TREATMENT OF ANAL DISORDERS

Examiner: Tate, Christopher Robin

Art Unit: 1654

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the U.S. patent references (Ref. Nos. 1-24) are not submitted [in compliance with the requirements of 1287 OG 163].

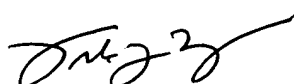
In accordance with 37 CFR 1.95(d), copies of foreign patent Ref. Nos. 25-34 and non-patent Ref. Nos. 38-76 are to be found in U.S. Patent Appln. Nos. 08/250,555 (filed May 27, 1994, Patent No. 5,504,117, Atty. Ref. 010692-004500US); 08/371,088 (filed Jan. 10, 1995, abandoned, Atty. Ref. 010692-004510US); 08/666,264 (filed Jun. 20, 1996, Patent No. 5,693,676, Atty. Ref. 010692-004520US); 08/970,447 (filed Nov. 14, 1997, abandoned, Atty. Ref. 010692-004530US); and 10/021,168 (filed Dec. 11, 2001, abandoned, Atty. Ref. 010692-

004531US). Additional copies of these references may be provided to the Examiner upon request. Copies of the remaining references (Ref. Nos. 33-35 and 77-104) are submitted herewith. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This Statement is submitted concurrently with a Request for Continued Examination. Accordingly, no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft  
Reg. No. 46,946

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PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

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**Complete if Known**

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1654
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

**U.S. PATENT DOCUMENTS+**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	1	US-814,408		03-06-1906	Steele	
	2	US-2,840,080		06-24-1958	Clark	
	3	US-3,419,571		12-31-1968	Di Carlo et al.	
	4	US-4,118,480		10-03-1978	Williams	
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	6	US-4,292,299		09-29-1981	Suzuki et al.	
	7	US-4,371,516		02-01-1983	Gregory et al.	
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	22	US-5,595,753		01-27-1997	Hechtman	
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	24	US-5,693,676		12-07-1997	Gorfine	

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	25	DE	304,730	03-01-1989	Dunzendorfer et al.		<input type="checkbox"/>
	26	AU	74545/94	08-19-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	27	AU	PM 0971	03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	28	AU	PM 4247	03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	29	AU	PM 6395	07-14-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	30	DE	4,038,203	06-04-1992	Bonnacker et al.		<input type="checkbox"/>
	31	JP	62-67017	03-26-1987	Sawai et al.		<input type="checkbox"/>
	32	WO	98/36733	08-27-1998	Kamm, Michael Albert et al.		<input type="checkbox"/>

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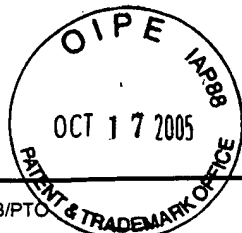
Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/669,099
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				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1654
				Examiner Name	Tate, Christopher Robin
Sheet	2	of	7	Attorney Docket Number	010692-004532US

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		Number <sup>4</sup>						
		Country Code <sup>3</sup>	Kind Code <sup>5</sup> (if known)					
	33	WO	95/06466	A1	03-09-1995	Koren Laboratories Pty., Ltd.		
	34	ZA	77/01135		02-25-1977	Prinsloo, J.		
	35	JP	04-091036		03-24-1996	Hashioka Tatsuya		
	36	WO	87/03490		06-18-1987	Key Pharmaceuticals, Inc.		
	37	WO	98/37886		09-03-1998	Antropoli		

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Sheet	3	of	8	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	38	Ahner et al., "Organic Nitrate Esters: Clinical Use and Mechanisms of Actions." <i>Pharmacol. Reviews</i> 43(3):351-353 (1991).	
	39	Budavari et al. (Eds.), "The Merck Index." pp. 198 and 821 (isopropyl nitrate); 11th Edition, Merck & Co., Rahway, N.J. (1989)	
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Examiner Signature	Date Considered
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	53	Huff et al., (Eds.), "Physicians' Desk Reference." 41st Edition, Medical Economics Company, Oradell, N.J., at pp. 780, 1176-1178, 1533 and 1984-85 (1987)		
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	69	O'Kelley, T. <i>et al.</i> , "Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide." <i>Gut</i> , 34: 689-693 (1993)	
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	85	"Glyceryl trinitrate for anal fissure?" <i>Drug and Therapeutics Bulletin</i> ; 36:55-6 (1998)	
	86	Gorfine, S.R. "Topical nitroglycerin ointment for anal fissures and ulcers." <i>New England Journal of Medicine</i> ; 333: 1156-7 (1995)	
	87	Hattori, K. et.al. "Fissure treatment in day surgery days." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)	
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	95	Maria, "Identification of anti-endothelial cell antibodies in patients with chronic anal fissure." <i>Surgery</i> , 126:535-40 (1999)	
	96	Mazier, "Hemorrhoids, fissures, and pruritus ani." <i>Anorectal Surg.</i> , 74(6):1277-92 (1994)	
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Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1654
Examiner Name	Tate, Christopher Robin				
Attorney Docket Number	010692-004532US				
Sheet	7	of	8		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	101	Schouten, "Relationship between anal pressure and anodermal blood flow: The vascular pathogenesis of anal fissures." <i>Dis. Col. Rect.</i> , 37(7):664-9 (1994)		
	102	Schouten, "Ischaemic nature of anal fissure." <i>Br. J. Surg.</i> , 83:63-5 (1996)		
	103	Simons, A.J. et al. "Glyceryl trinitrate for anal fissure." <i>Lancet</i> , 348:491-2 (1996)		
	104	Suda, K. et.al. "Application of nitroglycerin ointment on post-hemorrhoidectomy pain." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)		

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